



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,333	02/21/2001	Lanfranco Callegaro	204,940	9321

7590 04/06/2004

Abelman Frayne & Schwab
150 East 42nd Street
New York, NY 10017-5612

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,333	Applicant(s) CALLEGARO ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-32 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-32 and 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicant's response, filed on January 6, 2004, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 25-32 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorigatti et al. (WO 94/17837) in view of Valentini et al. (U.S. Patent 5,939,323).

Dorigatti et al. provides a multilayer nonwoven material comprising a layer coming in contact with the skin and selected from the group consisting of a derivative of hyaluronic acid, specifically a hyaluronic acid ester, and a perforated membrane compatible with cell growth on its surface (See p. 2, lines 16-34). Dorigatti et al. teaches that the perforated membrane may include glycosaminoglycans (See p. 6, lines 13-29) and the nonwoven tissue can be impregnated with pharmaceutically active compounds and be used in surgery because of its antiadhesive properties (See p. 7, lines 16-28).

Thus, with regard to claims 25, 34 and 39-44, the international publication provides the general teachings that cells can be grown on nonwoven material comprising hyaluronic acid esters and/or a perforated membrane comprising glycosaminoglycans, i.e., hyaluronic acid, and the material

Art Unit: 1615

may be used in surgeries, where its antiadhesive properties are required. Dorigatti et al. is deficient in the sense, that the publication does not specify the type of cells, which may be grown on the material of the invention.

With respect to claims 26-32 and 35-38, Dorigatti et al. teaches that hyaluronic acid esters are preferred in the layer contacting the skin (See p. 2, lines 30-34), and includes the esters of hyaluronic acid disclosed in U.S. Patent 4,851,521 and comprising esters of hyaluronic acid with alcohols, sulphonic acids and neutral sulphates, among the hyaluronic acid esters used in the invention (See p. 4, lines 26-29).

Valentini et al. provides derivatives of HA as raw material to fabricate porous, degradable scaffolds for tissue repair and wound healing (See col. 1, lines 64-67). Valentini et al. teaches that the scaffolds can have any size and shape and can be used for attachment of bioactive molecules (See col. 2, lines 7-22). Valentini et al. teaches that most preferably the HA derivative is HA esterified with a benzyl moiety (See col. 2, lines 54-67). Valentini et al. teaches that the scaffolds may be used for the treatment of damage resulting from intestinal cancer or intestinal ulcer, can be seeded with intestinal cells and utilized to promote tissue culture (See col. 7, line 52 to col. 8, line 17).

Thus, Valentini et al. provides HA matrices for the ingrowth of intestinal cells.

Art Unit: 1615

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Dorigatti et al. with the teachings of Valentini et al. to grow intestinal cells on nonwoven material. The expected result would have been a successful biological material and successful process for preparing said material. Because of the teachings of Dorigatti et al., that nonwoven material comprising hyaluronic acid esters and/or a perforated membrane may be used in medical application for cell ingrowth, and the teachings of Valentini et al., that derivatives of HA can be seeded with intestinal cells to promote tissue culture and treat damage resulting from intestinal ulcer, one of ordinary skill in the art would have a reasonable expectation that the process and compositions claimed in the instant application would be successful in providing a biological material for the treatment of ulcers and intestinal lesions. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

3. Applicant's arguments filed on January 6, 2004 have been fully considered but they are not persuasive.
4. Applicant argues that Dorigatti et al. discloses a multilayer material and fails to teach a single layer non-woven material or perforated membrane. In response to said argument, it is noted that the claims in the instant application do not read on a single layer material.
5. In response to Applicant's argument, that Dorigatti et al. provides a composition for repairing wounds, it is noted that Dorigatti et al. clearly discloses a perforated membrane

Art Unit: 1615

compatible with cell growth on its surface, and teaches that the material can be used in a variety of medical applications, including surgery (See p. 2, lines 30-31 and Abstract). Thus, the invention of the prior art is not limited to wound repair.

6. In replay to Applicant's argument, that Valentini et al. teaches the presence of interconnected pores, it is noted that Dorigatti et al. provides the general teachings that perforated membranes comprising hyaluronic acid may be used for growing cells. Valentini et al. is relied upon for the teachings that matrices of hyaluronic acid can be seeded with intestinal cells. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

7. In response to Applicant's argument, that any type of cells has its own particular properties and characteristics, so that growth can be stimulated on a matrix, but not on another, the burden is shifted to Applicant to show that the matrix disclosed by Dorigatti et al. would not be capable of stimulating the growth of intestinal cells.

Conclusion

8. Claims 25-32 and 34-44 are rejected.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sen3

April 1, 2004

Thurman X. Page
THURMAN X. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600